TABLE 2. Tests for hepatitis C virus (HCV) infection

Test/Type	Application	Comments
Hepatitis C virus antibody (anti-HCV)		
• EIA (enzyme immunoassay) • Supplemental assay (i.e., recombinant immunoblot assay [RIBA™])	• Indicates past or present infection, but does not differentiate between acute, chronic, or resolved infection • All positive EIA results should be verified with a supplemental assay	• Sensitivity ≥97% • EIA alone has low-positive predictive value in low-prevalence populations
HCV RNA (hepatitis C virus ribonucleic acid)		
Qualitative tests*†		
• Reverse transcriptase polymerase chain reaction (RT-PCR) amplification of HCV RNA by in-house or commercial assays (e.g., Amplicor HCV™)	• Detect presence of circulating HCV RNA • Monitor patients on antiviral therapy	• Detect virus as early as 1–2 weeks after exposure • Detection of HCV RNA during course of infection might be intermittent; a single negative RT-PCR is not conclusive • False-positive and false-negative results might occur
Quantitative tests*†		
• RT-PCR amplification of HCV RNA by in-house or commercial assays (e.g., Amplicor HCV Monitor™) • Branched chain DNA§ (bDNA) assays (e.g., Quantiplex™ HCV RNA Assay)	• Determine concentration of HCV RNA • Might be useful for assessing the likelihood of response to antiviral therapy	• Less sensitive than qualitative RT-PCR • Should not be used to exclude the diagnosis of HCV infection or to determine treatment endpoint
Genotype*†		
• Several methodologies available (e.g., hybridization, sequencing)	• Group isolates of HCV based on genetic differences, into 6 genotypes and >90 subtypes • With new therapies, length of treatment might vary based on genotype	• Genotype 1 (subtypes 1a and 1b) most common in United States and associated with lower response to antiviral therapy
Serotype*		
• EIA based on immunoreactivity to synthetic peptides (e.g., Murex HCV Serotyping 1–6 Assay)	• No clinical utility	• Cannot distinguish between subtypes • Dual infections often observed

* Currently not U.S. Food and Drug Administration approved; lack standardization.
† Samples require special handling (e.g., serum must be separated within 2–4 hours of collection and stored frozen [-20 C or -70 C]; frozen samples should be shipped on dry ice).
§ Deoxyribonucleic acid.